

“RECORD” study is not expected to be completed for 2 more years—until the summer of 2009. That’s a long time from now when you have millions of American’s taking this drug.

Second, there is something I would like to clarify. We have been reading this week that the FDA was not in a position to tell the American people about its concerns with Avandia because it needed “conclusive” information. That doesn’t make sense to me. The preliminary findings of the FDA’s ongoing “meta-analysis” of the Avandia clinical trials have been consistent with Dr. Nissen’s findings of an increased heart attack risk, as well as the drug maker’s findings. It goes like this: the drugmaker sees a 31-percent increased risk of a heart attack; the FDA sees a 40-percent increased risk for heart attacks; and Dr. Nissen sees a 43-percent increased risk for heart attacks. Those numbers seem like a high enough threshold to me for the FDA to warn the American people of the possibility of a problem.

Third, several months ago, the Division of Drug Risk Evaluation, which sits within the Office of Surveillance and Epidemiology, recommended a “boxed” warning for Avandia. Why? Because it was believed that Avandia increased the risk of heart attacks. To date, FDA has not acted on upon this recommendation.

In a statement I released on Tuesday, I also pointed out that about a year ago some FDA scientists recommended a black box warning for congestive heart failure. There is still no black box warning for congestive heart failure, and I understand that happened because the office that put Avandia on the market in the first place wanted to look into it further. America is still waiting for a decision.

It was also reported to me that the incidence of heart attacks with Avandia could be about 60,000 to 100,000 from 1999 to 2006. That is a lot. Just doing the math and using conservative numbers, that means about 20 or more unnecessary heart attacks a day.

At a minimum, I think that the office responsible for post marketing safety needs to have the ability to warn Americans when it thinks it needs to do so. If not, we have what we have here today, delays in telling the American people about a possible serious safety problem. It is not right, and I am going to keep working to change things once and for all. The FDA legislation passed by the Senate two weeks ago dropped the ball on this important reform. The Avandia case sets it up for the House of Representatives to give real clout to the FDA office that monitors and assesses drugs after they are on the market and taken by millions of people. If the Office of New Drugs continues to call all the shots, like it does today, then it is more status quo and less public safety from the FDA. Both the evidence and the experts underscore the need for real reform here.

One opportunity to improve upon postmarketing drug safety stems from

the Access to Medicare Data Act that I filed today with Senator BAUCUS. This bill is based on S. 3897, the Medicare Data Access and Research Act, which Senator BAUCUS and I introduced in the 109th Congress. The purpose of the bill is to provide federal health agencies and outside researchers more sources of data for examining adverse events so that serious safety questions are identified promptly and timely action can be taken to protect American consumers.

SENATE SPOUSES

Mr. WARNER. Mr. President, Tuesday, May 22 was a memorable day in the life of the U.S. Senate. In keeping with longstanding tradition, each year, Senate spouses gather to give a luncheon in honor of the First Lady of the United States of America.

Last year, Landra Reid served as Chairman and Jeanne Warner served as co-chairman. The theme was a unique one, entitled, “100 Dresses.” This year, Jeanne Warner became Chairman, Grace Nelson became co-chairman and Landra Reid, together with over 20 Senate spouses, organized another highly successful and enjoyable luncheon. This year’s event, entitled “Heartfelt Safari,” focused on the President and Mrs. Bush’s initiative to help alleviate the plight of malaria in Africa. The number of deaths this year from malaria could be as high as two million, largely among children in Africa. Part of the proceeds from the luncheon will be donated to a well-respected not-for-profit charity—Malaria No More—that works to alleviate this tragic suffering.

In the evening, our two Senate leaders presided over a dinner honoring the Senate spouses. Senator REID opened with a moving framework of remarks, humorously recounting how the esteemed author, Ralph Waldo Emerson, once spoke for over 2 hours at a Harvard University event in the 1830s. He quickly assured the audience he would not seek to match Emerson, and he then proceeded to give a very warm introduction of an honored guest, Placido Domingo. The renowned singer regaled the audience with anecdotes about his career and about America’s growing interest in opera.

Senator McCONNELL concluded the evening, reciting the vital role performed by Senate spouses through the years. His remarks were warmly received by so many colleagues that I am privileged to offer for the RECORD, on behalf of all Senators, his thoughts, and I ask unanimous consent they be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

SENATE LEADERS HONORING SPOUSES—REMARKS AS PREPARED FOR LEADER McCONNELL

A few weeks after marrying Grace Cavert in 1972, Bill Nelson and his new bride hit the campaign trail for the first time. Neither of

them could have imagined that 35 years later, Bill would be known throughout the halls of power in Washington as the husband of Grace Nelson.

Grace is a real sign of contradiction in this town. She believes in bringing people together, across party lines, and she’s backed that belief up with deeds. As head of the Spouses of the Senate, she’s been a model of how to practice bipartisanship and how to make it work. In retrospect, we probably should have consulted with her on the immigration bill.

I happen to know firsthand that Grace and all the other wives are a warm, welcoming group. Because my wife, who happens to be a pretty busy woman in her own right, is a regular at their Tuesday lunches, Elaine appreciates the friendships she’s formed there, and she counts on the advice she can get from all of you on matters of vital concern, like where to find a decent electrician.

Jeanne Warner, thanks for organizing the First Lady’s lunch today and for securing this beautiful garden for tonight’s event. To the performers: Joyce Bennett, Barbara Levin, and, of course, our special guest, Placido Domingo, thanks. Thank you for sharing your talented young artists with us tonight.

No less a historian than our own Robert Byrd has called the Senate a place of “resounding deeds.” But any time one of us writes a memoir, it’s always the quiet deeds of a devoted spouse that the senators themselves seem to marvel at the most.

Senator Byrd himself can boast more milestones than any other senator in U.S. history. But he’ll tell you his proudest achievement, his most resounding deed, was that he married a coal-miner’s daughter named Erma and that they stayed together longer than any Senate couple in history.

One of Senator Reid’s predecessors, Mike Mansfield, was a high-school dropout when his wife Maureen convinced him to go back to school—and then sold her own life insurance policy to pay for it. More than 70 years later, after one of the most distinguished political careers in U.S. history, Mansfield was invited back to the Capitol to receive one last honor. He could have recalled a thousand legislative deals. But when it came his turn to speak, he praised Maureen instead.

Here’s what he said: “The real credit for whatever standing I have achieved in life should be given to my wife Maureen. She was and is my inspiration. She gave of herself to make something of me. She made the sacrifices and really deserved the credits, but I was the one who was honored. She has always been the better half of our lives together and without her coaching, her understanding, and her love, I would not be with you tonight. What we did, we did together. In short, I am what I am because of her.”

Barry Goldwater was another one who knew where to place the credit. He’d proposed to his future wife Peggy many times before they found themselves in a phone booth on a cold New Year’s Eve night in Muncie, Indiana, in 1933. Peggy wanted to call her mother to wish her a Happy New Year, and while they were standing there, Barry said he was running out of quarters and patience. He asked her to marry him one more time, she said yes, and nearly half a century later, Barry Goldwater wrote this postscript to a long and storied career:

“There are many moments of triumph in a man’s lifetime which he remembers. I have been to the mountaintop of victory—my first election to the Senate, and my reelection, that night in Chicago, in 1960, when the governor of Arizona put my name in nomination for the office of the President of the United States; and another night in San Francisco when the delegates to the Republican Convention made me their nominee. But above all these I rate that night in Muncie.”

Ronald Reagan once said there was only one person in the world that could make him lonely just by leaving the room. And we learned earlier this week that Nancy still marvels at her husband's devotion. She shouldn't. Those of us who are fortunate to share this life of highs and lows, of forced smiles and cancelled plans, of bland buffets and late night calls, know we couldn't achieve much at all, much less resounding deeds, without the person sitting next to us.

ACCOUNTABILITY IN HIGHER EDUCATION

Mr. ALEXANDER. Mr. President, our country does not have just some of the best colleges and universities in the world. It has almost all of them. Our higher education system is our secret weapon in America's competition in the world marketplace. It is the cornerstone of the brainpower advantage that last year permitted our country to produce thirty percent of the world's wealth, measured by gross domestic product—for just 5 percent of the world's people.

Education Secretary Margaret Spellings, to her credit, established a commission 2 years ago to examine all aspects of higher education to make certain that we do all we can to preserve excellence in this secret weapon and access to it. Among other things, the commission called for more accountability in higher education.

The commission got the part about accountability right. We in Congress have a duty to make certain that the billions we allocate to higher education are spent wisely.

Unfortunately, the commission headed in the wrong direction when it proposed how to achieve accountability. In its report, and in the negotiated rule-making process, the Department of Education proposed a complex system of accountability to tell colleges how to accept transfer students, how to measure what students are learning, and how colleges should accredit themselves.

I believe excellence in American higher education comes from institutional autonomy, markets, competition, choice for students, federalism and limited Federal regulation.

The Department is proposing to restrict autonomy, choice, and competition.

Such changes are so fundamental that only Congress should consider them. For that reason, if necessary, I will offer an amendment to the Higher Education Act to prohibit the Department from issuing any final regulations on these issues until Congress acts. Congress needs to legislate first. Then the Department can regulate.

Instead of pursuing this increased Federal regulation, I have suggested to the Secretary a different course.

First, convene leaders in higher education—especially those who are leading the way with improved methods of accountability and assessment and let them know in clear terms that if colleges and universities do not accept

more responsibility for assessment and accountability, the Federal Government will do it for them.

Second, establish an award for accountability in higher education like the Baldrige Award for quality in American business. The Baldrige Award, granted by the Department of Commerce, encourages a focus on quality in American business. It has been enormously successful, causing hundreds of businesses to change their procedures to compete for the prize. I believe the same kind of award—or awards for different kinds of higher education institutions—would produce the same sort of result for accountability in higher education.

Finally, make research and development grants to states, institutions, accreditors and assessment researchers to develop new and better appropriate measures of accountability.

This combination of jawboning, creating a Baldrige-type prize for accountability and research and development for better assessment techniques will in, my judgment, do a better and more comprehensive job of encouraging accountability in higher education than anything Federal regulation can do.

If I am wrong, then we in Congress and the U.S. Department of Education can step in and take more aggressive steps.

Are there some things wrong with the American higher education system? Of course.

And in my testimony in Nashville last year before the Secretary's Commission on the Future of Higher Education I detailed some of them.

One is the failure of colleges of education to prepare school leaders to raise our k-12 system to the level of our higher education system.

Two is the growing political one-sidedness that has infected many campuses. Too often true diversity of thought is discouraged in the same of a preferred brand of diversity.

Third, is the rising cost of tuition and large amount of students debt although costs are lower than most Americans realize and the reason for the increase is primarily the State failure to fund higher education because of all the money that is being soaked up by rising medicaid costs.

Fourth, there is no doubt that colleges and universities are not as efficient as they should be. Campuses are too vacant in the summer. Faculty teaching loads are too light. And semesters are too short to justify the large expenditures.

Fifth, no one in Washington takes a coordinated look at the tens of billions of dollars spent for higher education. Secretary Spellings is the first to do this, and I applaud her for it, although I had hoped the result would have been less regulation, not more.

Finally, deregulation. There is too much Washington DC, regulation.

Instead of debating how many more regulations we need, if we really are se-

rious about excellence and opportunity, we should be debating which regulations we can get rid of.

The question is whether you believe that excellence in higher education comes from institutional autonomy, markets, competition, choice for students, federalism and limited Federal regulation or whether you don't.

I believe it does. In fact, I have spent most of my public career arguing that we should borrow these principles from higher education where we have excellence and try them in k-12 where we too often don't.

There is plenty of evidence that America's secret weapon is our system of colleges and universities. More Americans go to college than in any country. Most of the best universities of the world are in our country, attracting 500,000 of the brightest students from outside America—many of whom stay to create more good jobs for Americans.

Just a few short weeks ago, after two years of work, the Senate passed the America Competes Act. It authorizes investing \$62 billion over 4 years to help our country keep its brainpower advantage so we can keep jobs from going to India and China.

In China, India, in Europe and Latin America countries seeking to improve the incomes of their citizens are seeking to emulate our college and universities because they know that better schools and colleges mean better jobs. The former Brazilian President, Fernando Henrique Cardoso, recently told a group of Senators that the strongest memory of the United States he would take back to his country is the American University. "The uniqueness, strength and autonomy of the American university," Dr. Cardoso said, "There is nothing like it in the world." "Autonomy" is the key word in Dr. Cardoso's response.

Deregulating higher education and preserving the autonomy of its institutions—not more Washington, DC, regulation—is the key to preserving the quality of this secret weapon in our effort to keep our high standard of living.

The United States system of higher education is a remarkable system of 6,000 autonomous institutions. Some are public, like the University of Tennessee of which I was once President. Some are private like Vanderbilt and New York University, from which I graduated. Some are Catholic. Some are Jewish. Some are non profit. Some are for profit. Some, like UCLA, are research universities.

Some are trade schools like the Nashville Auto Diesel College which graduate 1300 of the best auto mechanics in the world each year. Some are 2-year community colleges or technical institutes.

Some, like the University of Texas, have 100,000 students. Some, like Valley College in West Virginia have 34 students.

Some like Harvard, have 20,000 applicants for 1,700 freshman places. Some,